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09/830,338	07/11/2001	Johe Ikeda	2001-0515A	6935

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,338

Applicant(s)

IKEDA ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment along with the microorganism deposit receipt is acknowledged; claims 1, 12, and 16 are amended.

Claims 1-4, and 12-19 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 112***

Claims 2-4, 13-15, and 17-19 **remain rejected** under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 2-4, 13-15, 17-19 recite specific cell lines producing monoclonal antibodies. The microorganism deposit receipt statement is acknowledged and it is also noted that the deposits have been made under the International Budapest Treaty. However, this rejection is still maintained because the Office has not received from applicant the statement in bold below. Since the deposit is made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent**, would satisfy the deposit requirements. See 37 CFR 1.808.

The rejection of claims under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **withdrawn** since the amended claims are drawn to kit containing two antibodies recognizing different epitopes of NAIP.

***Claim Rejections - 35 USC § 102***

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by WO 97/26331 is **withdrawn** because the art does not teach anti-NAIP monoclonal antibodies that bind to the epitopes i.e. amino acids 256-586, or 841-1052 of NAIP (SEQ ID NO:1). However, WO 97/26331 will be used as the primary reference for claim rejection under 35 U.S.C. 103(a). Note below.

***Claim Rejections - 35 USC § 103***

Claim 1 is **newly rejected** under 35 U.S.C. 103(a) as being unpatentable over WO 97/26331 (cited in ISR and previous Office action) in view of Roy et al (, Dec 1, 1997, EMBO J., vol. 16, pages 6914-25) and further in view of US Pat. 6,511,828 B1 (published Jan 28, 2003 with filing date of **May 31, 1996**).

The claim is interpreted as drawn to NAIP monoclonal antibodies that bind to the epitopes i.e. amino acids 256-586, or 841-1052 of NAIP (SEQ ID NO:1).

As stated in the previous Office action mailed on 01-15-2003, WO 97/26331 teaches (pages 6 and 7, 21-24 especially, page 22 line 7 from the bottom of the page) monoclonal NAIP antibodies, and also teach a protein identical to the instant SEQ ID NO:1.

The primary reference does not teach monoclonal antibody with the specific binding epitopes i.e. amino acids 256-586, or 841-1052 of NAIP.

However, Roy et al teach human NAIP belongs to IAP protein family that are important for regulation of cellular apoptosis, and that BIR motif of IAP protein family is important for biological function(s) of the protein family (note the Introduction and abstract), and Roy et al further teach that deletion in NAIP is detected with most severe form of spinal muscular atrophy (note the paragraph bridging pages 6914 to 6915).

Roy et al do not explicitly disclose where the biologically important BIR motif is located in the human NAIP, therefore US Pat. 6,511,828 is cited to show that the biologically important BIR motif lies within the epitopes the instantly claimed monoclonal antibody binds to, namely amino acid 276-349 of instant SEQ ID NO:1 (human NAIP). That patent at Fig. 3A, last row, teaches amino acid 276-349 of instant SEQ ID NO:1 is the biologically important BIR motif as taught by the secondary reference of Roy et al. Note the attached sequence alignment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make antibody that binds to biologically important epitopes as taught by Roy et al with a reasonable expectation of success.

Claims 12, 14-16, 18, and 19 **remain rejected** for under 35 U.S.C. 103(a) as being unpatentable over WO 97/26331 in view of Roy et al (Déc 1, 1997, EMBO J., vol. 16, pages 6914-25) and further in view of US Pat. 6,511,828 B1 (published Jan 28, 2003 with filing date of **May 31, 1996**) as applied to claim 1 above, and further in view of

Harlow et al (1988, Antibodies A Laboratory Manual, Cold Spring Harbor Laboratory, pages 556, 558, 579-81 only).

Applicant argues that that amended claims are obvious because the primary reference WO 97/26331 does not specifically point out the recited epitopes i.e. amino acids 256-586, or 841-1052 of NAIP (SEQ ID NO:1). The argument has been fully considered but found unpersuasive for the reasons given above in rejection of the newly amended claim 1 under 103(a).

### **Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
December 26, 2003

  
MISOOK YU, Ph.D.  
EXAMINER  
TECHNOLOGY CENTER  
703-308-2454